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Attorney Docket No. P63187US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Philippe Du MESNIL et al.

Serial No.: 10/722,467 Group Art Unit: 1617

Filed: November 28, 2003 Examiner: Leonard M. Williams

For: **PROCESS FOR TREATING LAMENESS BY ADMINISTRATION OF A BISPHOSPHONIC ACID DERIVATIVE**

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The undersigned, Dominique Thibaud, does hereby declare and state that:

1. He is a citizen of France residing in the United States at 14312 Farley Street, Overland Park, Kansas.
2. He is a named inventor of the subject application.
3. He is a Doctor in Veterinary Medicine, currently holding the title and position Director of Development and Pharmaceutical Regulatory Affairs, North America, at Ceva Animal Healthy USA, Inc.
4. He is familiar with the final rejection (mailed August 17, 2007) of claims 12-20 (set forth, therein) under 35 USC 103(a) for allegedly having been obvious over Biere (US 4,473,560), Barbier (US 5,488,041) and Siris (*The American Journal of Medicine 101; 1996, 339-340*) (hereafter "rejection").
5. With respect to the rejection, he provides—as expert in the field of the invention—the following analysis and opinion:

   The rejected claims are directed to a treatment for lameness caused by osteoarthritis "in a human or animal" not suffering from fractures. The treatment—as claimed—requires administering to the human or animal a compound selected from

among multiple, specifically named bisphosphonic acid derivatives and their salts (hereafter, "bisphosphonic acid compound").

According to the rejection it would have allegedly been obvious to the skilled person to use the bisphosphonic acid compound as recited in the rejected claims, because Siris allegedly teaches Paget's disease (i) can induce osteoarthritis, (ii) causes localized bone pain, and (iii) is treatable in a human by administering a compound covered by the bisphosphonic acid compound.

Siris teaches only the treatment of human patients for Paget's disease since—as would be understood by the skilled artisan—only humans *can be treated* for Paget's disease. Paget's disease is a purely human affliction, having no equivalent in veterinary medicine. There is nothing cited in the prosecution history—nor could there be—showing that Paget's disease is an affliction of non-human animals. Therefore, the teachings of Siris are strictly limited to the treatment of human patients.

Per amendment to be filed concurrently herewith, the rejected claims are amended as in the attached Appendix. As indicated in the Appendix, claims 12-20, as amended, are limited to treatment of a non-human animal; thereby, rendering irrelevant—to amended claims 12-20—the teachings Siris (limited to humans), as relied on in the rejection.

Moreover, Siris teaches treating Paget's disease at an early stage, i.e., for the purpose of avoiding complications, such as osteoarthritis. Accordingly, patients treated according to Siris do not suffer from osteoarthritis, or from osteoarthritis-induced lameness, i.e., compounds are administered to prevent osteoarthritis—caused by Paget's disease—not to treat osteoarthritis. As a result, Siris neither teaches nor suggests the treatment of lameness caused by osteoarthrosis, as recited in the rejected (and amended) claims.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further declarant sayeth naught.

March 11, 2008
Date

Dominique Thibaud

US10762447 Rule 132(Thibaud).wpd

Appendix

12 (currently amended): Process for treating lameness caused by osteoarthrosis comprising the administration, to a ~~human or to an~~ non-human animal not suffering from fractures, of an effective amount of a bisphosphonic acid derivative selected from the group consisting of:

- 1-hydroxyethylidenebisphosphonic acid and its sodium salts;
- 2-pyrid-2-ylethylidenebisphosphonic acid and its sodium salts;
- phenoxymethylenebisphosphonic acid and its salts;
- thiomorpholinomethylenebisphosphonic acid and its salts;
- 4-chlorophenylthiomethylenebisphosphonic acid and its salts;
- 1-hydroxy-2-(3-pyridyl)ethylidenebisphosphonic acid and its sodium salts;
- 1-hydroxy-2-(2-imidazolyl)ethyl-1,1-bisphosphonic acid and its salts; and
- 2-hydroxyethylidene-2-(3-pyridyl)-1,1-bisphosphonic acid and its sodium salts.

13 (previously presented): Process according to claim 12, for treating an animal belonging to the equidae family.

14 (previously presented): Process according to claim 12, for treating a horse.

15 (previously presented): Process according to claim 12, comprising the administration of 0.001 mg/kg/ to 100 mg/kg of body weight of the bisphosphonic acid derivative.

16 (previously presented): Process according to claim 12, for treating limps in horses, comprising the intravenous administration of 0.01 mg/kg/week to 1 mg/kg/week of tiludronic acid or one of its pharmaceutically acceptable salts.

17 (previously presented): Process according to claim 12, comprising the oral administration of the bisphosphonic acid derivative.

18 (previously presented): Process according to claim 12, comprising the parenteral administration of the bisphosphonic acid derivative.

19 (previously presented): Process according to claim 12, comprising the administration of the bisphosphonic acid derivative in the form of an implant.

20 (previously presented): Process according to claim 12, in which the bisphosphonic acid derivative is 4-chlorophenylthiomethylenebisphosphonic acid.